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FLEHR HOHBACH TEST ALBRITTON & HERBERT FOUR EMBARCADERO CENTER			NOGUEROLA, ALEXANDER STEPHAN	
SUITE 3400 SAN FRANCISCO, CA 941114187			ART UNIT	PAPER NUMBER
			1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

A)	3
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	Application No.	Applicant(s)
	09/440,371	BLACKBURN ET AL.
Office Action Summary	Examiner	Art Unit
	ALEX NOGUEROLA	1753
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet with	n the correspondence address
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a r - If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a repreply within the statutory minimum of thirty od will apply and will expire SIX (6) MONTI tute. cause the application to become ABA	oly be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133)
Status		
1) Responsive to communication(s) filed on		
	 his action is non-final.	
3) Since this application is in condition for allow		rs prosecution as to the merits is
closed in accordance with the practice unde		-
Disposition of Claims	,, .,	.,,
4)⊠ Claim(s) <u>1-30</u> is/are pending in the application	nn.	
4a) Of the above claim(s) is/are withdown		
5)⊠ Claim(s) <u>25-30</u> is/are allowed.	rawn nom consideration.	
6)⊠ Claim(s) <u>1-24</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and	/or election requirement	
Application Papers	•	
9) The specification is objected to by the Examin	nor	
10)⊠ The drawing(s) filed on <u>12 November 1999</u> is		bioated to by the Eventines
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the corre		· ·
11) The oath or declaration is objected to by the l		
Priority under 35 U.S.C. § 119	examiner. Note the attached	51110C 71011011 01 1011111 1 10-102.
<u> </u>		40() ()
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:	In priority under 35 U.S.C. § 1	19(a)-(d) or (f).
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 Copies of the certified copies of the pri application from the International Bure 		ceived in this National Stage
* See the attached detailed Office action for a list		anivad
occ the attached detailed Office action for a lis	st of the certified copies not re	ceived.
Attachment(s)	_	
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Sun	
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 10/09/2001. 	B) 5) Notice of Info	Mail Date rmal Patent Application (PTO-152)

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the porous electrode of claim 3 must be shown or the feature canceled from the claim. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrodes configured for mixing sample, as per claim 14, must be shown or the feature canceled from the claim. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, meāns an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

- 4. Claim 20 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 20 of prior U.S. Patent No. 6,264,825 B1. This is a double patenting rejection.
- 5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Double Patenting Rejections Based on U.S. Patent No. 6,264,825 B1

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 1 of U.S. Patent No. 6,264,825 B1. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the

scope of claim 1 of U.S. Patent No. 6,264,825 B1 includes all of the limitations of claim 1 of the

instant application. The only difference between claim 1 of U.S. Patent No. 6,264,825 B1 and

claim 1 of the instant application is that claim 1 of U.S. Patent No. 6,264,825 B1 further requires

the detection electrode to further comprise a self-assembled monolayer.

7. Claim 2 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 2 of U.S. Patent No. 6,264,825 B1. Claim 1, from

which claim 2 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 2 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 2 of the instant

application.

8. Claim 3 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claims 2 and 28 of U.S. Patent No. 6,264,825 B1. Claim 2,

from which claim 3 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 28 of U.S. Patent

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No. 6,264,825 B1, which is closely related to claim 2 of U.S. Patent No. 6,264,825 B1, requires the detection electrode to comprise weirs.

- 9. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,264,825 B1. Claim 2, from which claim 4 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 4 of the instant application.
- 10. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,264,825 B1. Claim 2, from which claim 7 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 5 of the instant application.
- 11. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,264,825 B1. Claim 4, from which claim 6 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of U.S. Patent

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No. 6,264,825 B1 requires the same additional limitation as does claim 6 of the instant

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application.

12. Claim 7 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 6 of U.S. Patent No. 6,264,825 B1. Claim 4, from

which claim 7 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 6 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 7 of the instant

application.

13. Claim 8 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 8 of U.S. Patent No. 6,264,825 B1. Claim 1, from

which claim 8 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 8 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 8 of the instant

application.

14. Claim 9 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 9 of U.S. Patent No. 6,264,825 B1. Claim 1, from

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which claim 9 depends, has been addressed above. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because claim 9 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 9 of the instant

application.

15. Claim 10 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 10 of U.S. Patent No. 6,264,825 B1. Claim 1, from

which claim 10 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 10 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 10 of the instant

application.

16. Claim 11 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 11 of U.S. Patent No. 6,264,825 B1. Claim 1, from

which claim 11 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 11 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 11 of the instant

application.

- 17. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,264,825 B1. Claim 1, from which claim 12 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 12 of the instant application.
- 18. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,264,825 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claim 13 of U.S. Patent No. 6,264,825 B1 includes all of the limitations of claim 13 of the instant application. The only difference between claim 13 of U.S. Patent No. 6,264,825 B1 and claim 13 of the instant application is that claim 13 of U.S. Patent No. 6,264,825 B1 further requires the detection electrode to further comprise a self-assembled monolayer.
- 19. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,264,825 B1. Claim 13, from which claim 14 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 14 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 14 of the instant application.

- 20. Claim 15 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,264,825 B1. Claim 14, from which claim 15 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 15 of the instant application.
- 21. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,264,825 B1. Claim 13, from which claim 16 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 16 of the instant application.
- 22. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,264,825 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claim 17 of U.S. Patent No. 6,264,825 B1 includes all of the limitations of claim 17 of the instant application. The only difference between claim 17 of U.S. Patent No. 6,264,825 B1 and claim 17 of the instant application is that claim 17 of U.S. Patent No. 6,264,825 B1 further requires the detection electrode to further comprise a self-assembled monolayer.

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23. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,264,825 B1. Claim 17, from

which claim 18 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 18 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 18 of the instant

application. Note that the examiner has assumed that Applicant intended for Claim 18 to depend

from claim 17, not from claim 7.

24. Claim 19 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 19 of U.S. Patent No. 6,264,825 B1. Claim 17, from

which claim 19 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 19 of U.S. Patent

No. 6,264,825 B1 requires the same additional limitation as does claim 19 of the instant

application. Note that the examiner has assumed that Applicant intended for Claim 18 to depend

from claim 17, not from claim 7.

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Double Patenting Rejections Based on U.S. Patent No. 6,290,839 B1

25. Claim 1 is rejected under the judicially created doctrine of obviousness-type double

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patenting as being unpatentable over claim 1 of U.S. Patent No. 6,290,839 B1. Although the

conflicting claims are not identical, they are not patentably distinct from each other because

the self-assembled monolayer presented in claim 1 of U.S. Patent No. 6,290,839 B1 may be

covalently attached to the detection electrode¹. See col. 21, ln. 17 – col. 23, ln. 51.

26. Claim 2 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 1 of U.S. Patent No. 6,290,839 B1. Claim 1, from

which claim 2 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 1 requires concentrating

the sample with as first electrode and a second electrode as required by claim 2.

27. Claim 4 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 6 of U.S. Patent No. 6,290,839 B1. Claim 2, from

which claim 4 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 6 requires the same

additional limitation as does claim 4 of the instant application.

¹ The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the

application defines an obvious variation of an invention claimed in the patent. In re Vogel,

- 28. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,290,839 B1. Claim 2, from which claim 5 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of U.S. Patent No. 6,290,839 B1 requires the same additional limitation as does claim 5 of the instant application.
- 29. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 6 of U.S. Patent No. 6,290,839 B1. Claim 4, from which claim 5 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of U.S. Patent No. 6,290,839 B1requires the same additional limitation as does claim 6 of the instant application.
- 30. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 23 of U.S. Patent No. 6,264,825 B1. Claim 4, from which claim 7 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 23 of U.S. Patent No. 6,264,825 B1 requires the same additional limitation as does claim 7 of the instant application. Note that claim 23 depends from claim 9 of U.S. Patent No. 6,264,825 B1 which only differs from claim 1 of U.S. Patent No. 6,264,825 B1 in that claim 9 is a method for

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detecting a target nucleic acid sequence while the target analyte in claim 1 is not restricted. Also

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note that claim 22 provides for the first electrode being a detection electrode, as does claim 6.

31. Claim 8 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claims 1 and 11 of U.S. Patent No. 6,290,839 B1. Claim 1,

from which claim 8 depends, has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 11 requires the same

additional limitation as does claim 1 of the instant application. Note that claim 11 depends from

claim 9 of U.S. Patent No. 6,264,825 B1 which only differs from claim 1 of U.S. Patent

No. 6,264,825 B1 in that claim 9 is a method for detecting a target nucleic acid sequence while

the target analyte in claim 1 is not restricted.

Claim Rejections - 35 USC § 112

32. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

33. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention:

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a) Claim 18 recites the limitation "hybridization accelerator" in line1. There is insufficient antecedent basis for this limitation in the claim; and

b) Claim 19 recites the limitation "hybridization accelerator" in line1. There is insufficient antecedent basis for this limitation in the claim

Claim Rejections - 35 USC § 102

34. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35. Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Henkins et al. (US 6,391,558 B1), which claims priority from provisional application 60/040949.

Henkins et al. teaches a method of detecting a target nucleic acid sequence in a sample comprising

a) directly hybridizing the target sequence to a capture probe covalently attached to a detection electrode to form an assay complex, wherein the assay complex is formed in the presence of a hybridization accelerator, wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 20, ll. 42-47, which teaches a working electrode; col. 22,

II. 26-35, claim 16, and col. 33, II. 59-67, which teach immobilizing/bonding a capture probe onto the working electrode; col. 34, II. 31-63; which teaches hybridization; and claim 1, step (b); col. 34, II. 1-11; and col. 35, II. 50-67, which teaches ETM); and

b) detecting the presence of the ETM using the detection electrode (col. 34, ll. 1-11; col. 35, ll. 50-65; and claim 1, step (e)).

Note that although Henkins et al. does not mention a hybridization accelerator this is implied as Henkins et al. teaches optimizing the hybridization by adjusting the ionic strength of the hybridization solution and by adding formamide to the solution (col. 34, 11. 53-66).

- 36. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Barton et al. (US 6,461,820 B1). Barton et al. teaches a substrate comprising a plurality of electrodes (col. 16, Il. 32-50 and col. 14, Il. 10-22) each comprising
- a) a self-assembled monolayer (col. 11, ln. 64 col. 12, ln.6 and col. 19, ln. 45 col. 20, ln. 7);
 - b) a capture ligand (col. 14, 11. 10-38); and
- c) an interconnect such that each electrode is addressable (implied by col. 14, ll. 39-44, which teaches making a measurement at each electrode of the multielectrode array).

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Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

38. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

39. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

40. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (US 6,461,820 B1) in view of Ackley et al. (US 6,099,803).

Addressing claim 1, Barton et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the target analyte (col. 23, ln. 60 col. 24, ln. 13) into a detection chamber (col. 18, ll. 43-52, which teaches a working compartment in the electrochemical cell) comprising a detection electrode (col. 18, ll. 43-50, which teaches a working electrode) comprising a covalently attached capture ligand (col. 24, ll. 5-13; col. 20, ll. 1-6; and col. 15, ln. 65 - col. 16, In. 21, which teach forming self-assembled monolayers on the working electrode);
- b) binding the target analyte to the capture ligand to form an assay complex (col. 6, ll. 19-22 (step (a)); col. 6, ll. 33-34 (step (f)); and col. 17, ln. 63 - col. 18, ln. 12), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 18, ll. 60-66); and
- c) detecting the presence of the ETM using the detection electrode (col. 20, ln. 45 col. 21, ln. 59).

Barton et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target analyte would then be concentrated. Ackley et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (col. 8, 11. 55-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Ackley et al. in the invention of Barton et al. because then

sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Addressing claims 2 and 4, as seen in figures 1A and 1B of Ackley et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, Ackley et al. teaches providing a permeation layer above the electrodes (col. 9, 1l. 57-58). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a permeation layer as taught by Ackley et al. in the invention of Barton et al. because as taught by Ackley et al. the permeation layer will prevent large charged entities from contacting the electrodes, reduces electrochemical degradation and minimizes adsorption of entities to the electrodes (col. 9, 1l. 57-67).

41. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1) in view of Ackley et al. (US 6,099,803).

Addressing claim 1, Lennox et al. teaches a method of detecting a target analyte in a sample comprising

a) introducing the target analyte into a detection chamber (col. 11, ll. 56-59 and Figure 6) comprising a detection electrode (col. 11, ll. 15-21, which teaches a biosensor electrode) comprising a covalently attached capture ligand (col. 5, ll. 26-31, which teaches covalently

attaching a bioreceptor substance to the electrode surface col. 11, 11. 21-28, which teaches forming self-assembled monolayers on the working electrode);

- b) binding the target analyte to the capture ligand to form an assay complex (col. 12, ll. 51-55), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 11, ln. 56 col. 12, ln. 23 and Figures 5A and 5B); and
 - c) detecting the presence of the ETM using the detection electrode (col. 12, 11, 43–61).

Lennox et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target analyte would then be concentrated. Ackley et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (col. 8, Il. 55-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Ackley et al. in the invention of Lennox et al. because then sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Addressing claims 2 and 4, as seen in figures 1A and 1B of Ackley et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, although not labeled as such the monolayer (54) in Lennox et al., to which the capture ligand is attached, can be construed as a permeation layer because "the chains

are sufficiently close packed and ordered to form an effective barrier to electron transfer, under biosensing conditions" (col. 10, II. 14-18). Also, Ackley et al. teaches providing a permeation layer above the electrodes (col. 9, II. 57-58). So another reason for providing a permeation layer is that it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a permeation layer as taught by Ackley et al. in the invention of Barton et al. because as taught by Ackley et al. the permeation layer will prevent large charged entities from contacting the electrodes, reduces electrochemical degradation and minimizes adsorption of entities to the electrodes (col. 9, II. 57-67).

42. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henkins et al. (US 6,391,558 B1), which claims priority from provisional application 60/040949, in view of Ackley et al. (US 6,099,803).

Addressing claim 1, Henkins et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the target analyte in a detection chamber (claim 1, step (a); Figures 2A and 2B; col. 20, ll. 43-47; col. 27, ll. 45-49; and col. 33, ln. 59 col. 34, ln. 11) comprising a detection electrode (col. 20, ll. 42-47, which teaches a working electrode) comprising a covalently attached capture ligand (col. 22, ll. 26-35; claim 16; and col. 33, ll. 59-67, which teaches immobilizing/bonding a capture probe onto the working electrode);
 - b) binding the target analyte to the capture ligand to form an assay complex (col. 34,

ll. 1-11; col. 35, ll. 39-49; claim 1, step (a); and claim 15), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (claim 1, step (b); col. 34, ll. 1-11; and col. 35, ll. 50-67); and

c) detecting the presence of the ETM using the detection electrode (col. 34, ll. 1-11; col. 35, ll. 50-65; and claim 1, step (e)).

Henkins et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target analyte would then be concentrated. Ackley et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (col. 8, Il. 55-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Ackley et al. in the invention of Henkins et al. because then sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Note that support for passages cited above from Henkins et al. (US 6,391,558 B1) to meet Applicant's claim 1 may be found in provisional application No. 60/040,949, from which Henkins et al. (US 6,391,558 B1) claims priority. See page 8, ln. 27 – page 9, ln.8; claims 1 and 23; page 10, ll. 15-23; page 11, ll. 3-10; page 18, ll. 10-29; and page 22, ln. 9 – page 24, ln. 7.

Addressing claims 2 and 4, as seen in figures 1A and 1B of Ackley et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, Ackley et al. teaches providing a permeation layer above the electrodes (col. 9, 1l. 57-58). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a permeation layer as taught by Ackley et al. in the invention of Henkins et al. because as taught by Ackley et al. the permeation layer will prevent large charged entities from contacting the electrodes, reduces electrochemical degradation and minimizes adsorption of entities to the electrodes (col. 9, 1l. 57-67).

43. Claims 1, 2, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (US 6,461,820 B1) in view of Heller et al. (US 6,238,624 B1).

Addressing claim 1, Barton et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the target analyte (col. 23, ln. 60 col. 24, ln. 13) into a detection chamber (col. 18, ll. 43-52, which teaches a working compartment in the electrochemical cell) comprising a detection electrode (col. 18, ll. 43-50, which teaches a working electrode) comprising a covalently attached capture ligand (col. 24, ll. 5-13; col. 20, ll. 1-6; and col. 15, ln. 65 col. 16, ln. 21, which teach forming self-assembled monolayers on the working electrode);
- b) binding the target analyte to the capture ligand to form an assay complex (col. 6, ll. 19-22 (step (a)); col. 6, ll. 33-34 (step (f)); and col. 17, ln. 63 col. 18, ln. 12), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 18, ll. 60-66); and
- c) detecting the presence of the ETM using the detection electrode (col. 20, ln. 45 col. 21, ln. 59).

Barton et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target analyte would then be concentrated. Heller et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (Figures 6 and 11a-11c)). Providing electronic sensing components is also disclosed (col. 6, 1l. 36-42). It would have been obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Heller et al. in the invention of Barton et al. because then sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Addressing claims 2 and 4, as seen in col. 7, 1l. 49-64; col. 21, 1l. 36-54; and col. 22, 1l. 1-13 of Heller et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, Heller et al. teaches providing a permeation layer in conjunction with the capture ligand (Figure 6). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a permeation layer as taught by Heller et al. in the invention of Barton et al. because as taught by Heller et al. the permeation layer will "reduce the adverse physical and chemical effects of electrolysis reactions" and allow "solvent"

molecules, small counter-ions, and electrolysis reaction gases to freely pass to and from the metal surface" (col. 13, ll. 28-36 and col. 16, ll. 43-51).

Addressing claim 7, counter ions, such as Na⁺ and Cl⁻, and buffer are disclosed by Heller et al. (col. 16, ll. 30-34; col. 30, ll. 38-46; and Figure 5).

44. Claims 1, 2, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1) in view of Heller et al. (US 6,238,624 B1).

Addressing claim 1, Lennox et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the target analyte into a detection chamber (col. 11, ll. 56-59 and Figure 6) comprising a detection electrode (col. 11, ll. 15-21, which teaches a biosensor electrode) comprising a covalently attached capture ligand (col. 5, ll. 26-31, which teaches covalently attaching a bioreceptor substance to the electrode surface col. 11, ll. 21-28, which teaches forming self-assembled monolayers on the working electrode);
- b) binding the target analyte to the capture ligand to form an assay complex (col. 12, ll. 51-55), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 11, ln. 56 col. 12, ln. 23 and Figures 5A and 5B); and
 - c) detecting the presence of the ETM using the detection electrode (col. 12, 11. 43-61).

Lennox et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target

analyte would then be concentrated. Heller et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (Figures 6 and 11a-11c)). Providing electronic sensing components is also disclosed (col. 6, 1l. 36-42). It would have been obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Heller et al. in the invention of Lennox et al. because then sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Addressing claims 2 and 4, as seen in col. 7, 1l. 49-64; col. 21, 1l. 36-54; and col. 22, ll. 1-13 of Heller et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, although not labeled as such the monolayer (54) in Lennox et al., to which the capture ligand is attached, can be construed as a permeation layer because "the chains are sufficiently close packed and ordered to form an effective barrier to electron transfer, under biosensing conditions" (col. 10, ll. 14-18).

Addressing claim 7, counter ions, such as Na⁺ and Cl-, and buffer are disclosed by Heller et al. (col. 16, 1l. 30-34; col. 30, 1l. 38-46; and Figure 5).

45. Claims 1, 2, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henkins et al. (US 6,391,558 B1), which claims priority form provisional application 60/040949, in view of Heller et al. (US 6,238,624 B1)

Addressing claim 1, Henkins et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the target analyte in a detection chamber (claim 1, step (a); Figures 2A and 2B; col. 20, Il. 43-47; col. 27, Il. 45-49; and col. 33, In. 59 col. 34, In. 11) comprising a detection electrode (col. 20, Il. 42-47, which teaches a working electrode) comprising a covalently attached capture ligand (col. 22, Il. 26-35; claim 16; and col. 33, Il. 59–67, which teaches immobilizing/bonding a capture probe onto the working electrode);
- b) binding the target analyte to the capture ligand to form an assay complex (col. 34, ll. 1-11; col. 35, ll. 39-49; claim 1, step (a); and claim 15), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (claim 1, step (b); col. 34, ll. 1-11; and col. 35, ll. 50-67); and
- c) detecting the presence of the ETM using the detection electrode (col. 34, ll. 1-11; col. 35, ll. 50-65; and claim 1, step (e)).

Henkins et al. does not mention concentrating the target analyte in the detection chamber, although it should be noted that when the target analyte binds to the capture ligand the target analyte would then be concentrated. Heller et al. teaches concentrating analyte in a chamber before performing an analysis of the analyte (abstract). A concentrating means is used to concentrate the analyte onto capture ligands on collection electrodes (Figures 6 and 11a-11c)). Providing electronic sensing components is also disclosed (col. 6, ll. 36-42). It would have been

obvious to one with ordinary skill in the art at the time the invention was made to concentrate target analyte as taught by Heller et al. in the invention of Henkins et al. because then sample will not be wasted through dilution and dispersion, but will be efficiently guided to selected analysis regions.

Note that support for passages cited above from Henkins et al. (US 6,391,558 B1) to meet Applicant's claim 1 may be found in provisional application No. 60/040,949, from which Henkins et al. (US 6,391,558 B1) claims priority. See page 8, ln. 27 – page 9, ln.8; claims 1 and 23; page 10, ll. 15-23; page 11, ll. 3-10; page 18, ll. 10-29; and page 22, ln. 9 – page 24, ln. 7.

Addressing claims 2 and 4, as seen in col. 7, ll. 49-64; col. 21, ll. 36-54; and col. 22, ll. 1-13 of Heller et al. the concentrating step involves using a first electrode and a second electrode to electrophoretically transport sample to a collection electrode, which is the first electrode.

Addressing claim 6, Heller et al. teaches providing a permeation layer in conjunction with the capture ligand (Figure 6). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a permeation layer as taught by Heller et al. in the invention of Henkins et al. because as taught by Heller et al. the permeation layer will "reduce the adverse physical and chemical effects of electrolysis reactions" and allow "solvent molecules, small counter-ions, and electrolysis reaction gases to freely pass to and from the metal surface" (col. 13, ll. 28-36).

Addressing claim 7, counter ions, such as Na⁺ and Cl-, and buffer are disclosed by Heller et al. (col. 16, 1l. 30-34; col. 30, 1l. 38-46; and Figure 5).

46. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1).

Addressing claim 13, Lennox et al. teaches a method of detecting a target analyte in a sample comprising

- a) introducing the sample into a detection chamber (col. 11, ll. 56-59 and Figure 6) comprising a detection electrode (col. 11, ll. 15-21, which teaches a biosensor electrode) comprising a covalently attached capture ligand (col. 5, ll. 26-31, which teaches covalently attaching a bioreceptor substance to the electrode surface col. 11, ll. 21-28, which teaches forming self-assembled monolayers on the working electrode);
- b) binding the target analyte to the capture ligand to form an assay complex (col. 12, ll. 51-55), wherein the assay complex further comprises at least one electron transfer moiety (ETM) (col. 11, ln. 56 col. 12, ln. 23 and Figures 5A and 5B); and
 - c) detecting the presence of the ETM using the detection electrode (col. 12, 11. 43-61).

Lennox et al. does not mention flowing the sample past the detection electrode. Lennox et al. does disclose, however, providing a second port on the detection chamber so that liquid can flow through the chamber (col. 11, ll. 29-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a second port because a sample source can then be continuously monitored or more easily regularly monitored, for example, body fluid during a medical treatment.

Addressing claim 21, Lennox et al. teaches a substrate comprising a plurality of electrodes (Figure 14) each comprising

- a) a self-assembled monolayer (claim 5 and col. 10, 11. 38-52);
- b) a capture ligand (claim 5 and Figure 14); and
- c) an interconnect such that each electrode is addressable (Figure 14 and col. 15, Il. 11-21, which teaches that the electrodes are independent of one another).

Although claim 5 of Lennox et al. does not mention using gold electrodes it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because Lennox et al. teaches gold electrodes in the preferred embodiment for forming the self-assembled monolayer (col. 10, Il. 38-42).

47. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1) as applied to claims 13 and 21 above, and further in view of Hill et al. (US 5,727,548).

Lennox et al. does not provide much detail on the substrate; in particular, having the substrate made of printed circuit board is not mentioned. Using a printed circuit board as a support for electrodes in a biosensor is known in the art. See in Hill col. 9, ln. 1-2, for example. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a printed circuit board in the invention of Lennox et al. because the photolithography and etching techniques used in the electronics industry for forming circuits on

printed circuit boards are well developed and have been successfully used and adapted for making micro-scale electrodes suitable for biological sensing electrodes. Furthermore, substrates made of printed circuit board material can be easily obtained or manufactured.

48. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1) as modified by Hill et al. (US 5,727,548) as applied to claim 22 above, and further in view of Caron et al. (US 5,505,321).

Lennox et al. as modified by Hill et al. does not mention a fiberglass printed circuit board. Caron et al. disclose a fiberglass printed circuit board (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a fiberglass printed circuit as taught by Caron et al. in the invention of Lennox et al. as modified by Hill et al. because the fiberglass circuit board of Caron et al. resists delamination and allows the formation of fine interconnection lines (col. 2, ll. 18-40).

49. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (US 6,478,939 B1) as applied to claims 13 and 21 above, and further in view of Michel (5,968,745). Lennox et al. does not provide detail on the substrate; in particular, using a plastic substrate for electrodes is not mentioned. Michel teaches using plastic as an electrode substrate in a biosensor (col. 2, ln. 14-18). It would have been obvious to one with ordinary skill in the art

at the time the invention was made to use plastic as taught by Michel in the invention of Lennox et al. because plastic is inexpensive and can be easily shaped as desired.

50. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (US 6,461,820 B1) in view of Hill et al. (US 5,727,548).

Barton et al. teaches a substrate comprising a plurality of electrodes (col. 16, ll. 32-50 and col. 14, ll. 10-22) each comprising

- a) a self-assembled monolayer (col. 11, ln. 64 col. 12, ln.64 and col. 19, ln. 45 col. 20, ln. 7);
 - b) a capture ligand (col. 14, ll. 10-38); and
- c) an interconnect such that each electrode is addressable (implied by col. 14, ll. 39-44, which teaches making a measurement at each electrode of the multielectrode array).

Barton et al. does not provide much detail on the substrate; in particular, having the substrate made of printed circuit board is not mentioned. Using a printed circuit board as a support for electrodes in a biosensor is known in the art. See in Hill col. 9, ln. 1-2, for example. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a printed circuit board in the invention of Barton et al. because the photolithography and etching techniques used in the electronics industry for forming circuits on printed circuit boards are well developed and have been successfully used and adapted for making micro-scale electrodes suitable for biological sensing electrodes. Furthermore, substrates made of printed circuit board material can be easily obtained or manufactured.

51. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (US 6,461,820 B1) as modified by Hill et al. (US 5,727,548) as applied to claim 22 above, and further in view of Caron et al. (US 5,505,321).

Barton et al. as modified by Hill et al. does not mention a fiberglass printed circuit board. Caron et al. disclose a fiberglass printed circuit board (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a fiberglass printed circuit as taught by Caron et al. in the invention of Barton et al. as modified by Hill et al. because the fiberglass circuit board of Caron et al. resists delamination and allows the formation of fine interconnection lines (col. 2, ll. 18-40).

52. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (US 6,461,820 B1) in view of Michel (US 5,694,932).

Barton et al. teaches a substrate comprising a plurality of electrodes (col. 16, ll. 32-50 and col. 14, ll. 10-22) each comprising

- a) a self-assembled monolayer (col. 11, ln. 64 col. 12, ln.6 and col. 19, ln. 45 col. 20, ln. 7);
 - b) a capture ligand (col. 14, ll. 10-38); and
- c) an interconnect such that each electrode is addressable (implied by col. 14, ll. 39-44, which teaches making a measurement at each electrode of the multielectrode array).

Barton et al. does not mention using a plastic substrate. Michel teaches using plastic as an electrode substrate in a biosensor (col. 2, ln. 14-18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use plastic as taught by Michel in the invention of Barton et al. because plastic is inexpensive and can be easily shaped as desired.

Notice of References Cited

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Allowable Subject Matter

- 54. Claims 25-30 are allowed.
- 55. The following is a statement of reasons for the indication of allowable subject matter:
 - a) Claim 25 requires (a) coating an adhesion layer onto a fiberglass substrate, and
 - (b) coating gold onto the adhesion metal.

Marks et al. (6,203,758 B1) discloses a glass substrate (col. 10, ll. 7-9), not a fiberglass substrate. Also, Marks et al. does not coat gold onto an adhesion metal; instead, gold is used as an adhesion layer. Gold is coated directly onto the substrate and then coated with copper (col. 10, ll. 40-66). It would not have been obvious to use copper as the adhesion layer because copper is used to protect the underlying gold coating.

Diebold et al. (US 5,437,999) discloses an electrode embodiment having an adhesion layer coated onto a fiberglass substrate; however, silver/silver chloride is coated onto the adhesion layer (col. 7, ll. 8-14), not gold. It would not have been obvious to coat gold onto the adhesion layer instead of silver/silver chloride because this embodiment is only for a reference electrode. Diebold et al. teaches that a fiberglass substrate having a copper adhesion layer should not be used in a working electrode because "it interferes with the electrochemical measurement" (col. 6, ln. 61 – col. 7, ln. 5). For this reason, also, even if gold were substituted for silver/silver chloride in the reference electrode, there would not be a plurality of gold electrodes made by (a) coating an adhesion layer

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onto a fiberglass substrate, and (b) coating gold onto the adhesion metal because the

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working electrode, which is the only other electrode Diebold et al. discloses as being on

the same substrate as the reference electrode (Figure 8a), should not have a fiberglass

substrate having a copper adhesion layer;

b) Claims 27 and 28 depend from allowable claim 25;

c) Claims 29: as discussed above for claim 25, Marks et al. teaches away from coating

gold on adhesion metal, as gold is used as adhesion metal for copper. Diebold et al. does

not disclose adding a self-assembled monolayer (SAM) comprising a capture ligand to

each electrode. It would not have been obvious to add a SAM to each electrode of

Diebold et al. because the working electrode is coated with an enzyme mixture, which is

selective for glucose, for example, and the reference electrode has a silver/silver chloride

layer; and

d) Claim 30 depends from allowable claim 29.

Any inquiry concerning this communication or earlier communications from the 56.

examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-

1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

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Alex Noguerola
03/02/2004